FEMA FACT SHEET

FAQ on Allocation Order Regarding Exports of Scarce PPE and Exemptions

FEMA published a Temporary Final Rule in the *Federal Register* on April 10th implementing the President's Memorandum, "Allocating Certain Scarce or Threatened Health and Medical Resource to Domestic Use." This order required review by FEMA of exports of five types of Personal Protective Equipment (PPE), also referred to as "covered materials," needed to respond to the COVID-19 emergency. The second notice provides guidance on the implementation for the allocation order, including exemptions to the order. This FAQ explains the allocation order and implementation.

What is this allocation order?

- The allocation order was published in response to the President's April 3rd Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resource to Domestic Use. The intent of the Memorandum and allocation order are to preserve scarce personal protective equipment for domestic use.
- The allocation order was published by FEMA on April 10, 2020. It is available on the *Federal Register* website, at this link. Subsequent guidance on the implementation of the order was published via a notice in the *Federal Register*, available for public viewing at this link.
- In general terms, the allocation order allows the Federal Emergency Management Agency (FEMA) Administrator to review exports of five types of scarce or threatened personal protective equipment (PPE) needed to respond to the COVID-19 emergency. These five types of PPE are referred to as "covered materials."
- When FEMA learns that an export of one or more covered materials is planned, FEMA will
 review the shipment and take one of the following three actions (or may take the actions in
 combination):
 - O FEMA may purchase part or all of the shipment, using a rated order under Title 1 of the Defense Production Act:
 - FEMA may return all or part of the shipment for distribution in the domestic supply chain; or
 - O FEMA may allow all or part of the shipment to proceed as planned for export.



Covered Materials: The five types of materials that are included in the allocation order are referred to throughout this FAQ as "covered materials." The covered materials are:

- N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;
- Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181;
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
- PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

At this point in time, if a shipment does not contain one or more of the five items listed above, it is not addressed in the allocation order, and no impacts to export are expected. FEMA may add additional materials to this list in the future.

How is FEMA implementing this order?

- FEMA is working closely with U.S. Customs and Border Protection (CBP) to implement this order.
- CBP will obtain information on shipments from the Automated Export System, including the
 description of items to be shipped and the intended destination of the shipment, and will use
 that information to identify shipments that may contain covered materials. CBP will detain these
 shipments for review and determination by FEMA.
- CBP will send information on the shipment, including any letter of attestation submitted regarding the shipment, for review by FEMA, with assistance from the Export Cargo Review Working Group (ECRWG).
 - The ECRWG includes representatives from FEMA, CBP, the Department of State, and the Department of Commerce.
 - **o** FEMA and the ECRWG will review the materials provided by CBP about each shipment and use that information (and any additional information provided or requested) to make a decision on the disposition of that shipment.

What authorities allow FEMA to take this action?

- Title I of the Defense Production Act (DPA) allows the President, and appropriately delegated agencies, to "allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense" (50 U.S.C. 4511(a)(2)).
- On March 27th, the President signed Executive Order 13911 on "Delegating Additional Authority Under the DPA with Respect to Health and Medical Resources to Respond to the Spread of



- COVID-19." Title 4 of this Executive Order gave the Secretary of Homeland Security the authority to implement Title 1 of the DPA. In turn, on April 1st, the Secretary of Homeland Security delegated this authority to the FEMA Administrator in DHS Delegation 09052 Rev 00.1, "Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency."
- On April 3rd, the President signed a Memorandum entitled "Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use." In the Memorandum, the President noted that "it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries" from diverting five types of covered material overseas. The Memorandum directed the Secretary of Homeland Security, through the Administrator of FEMA, to "use any and all authority available under section 101 of the [DPA] to allocate to domestic use, as appropriate" the five types of covered materials provided in the box, above.
- In response, on April 10th, the FEMA Administrator issued the allocation order, allowing FEMA review shipments of these covered materials prior to export.

What is the relationship between FEMA and CBP?

 FEMA and U.S. Customs and Border Protection (CBP) are working in close conjunction to implement this allocation order. When CBP identifies a shipment that may contain covered materials, CBP will hold that shipment, and forward information regarding the shipment to FEMA for a determination. After FEMA makes a determination, FEMA sends that determination to CBP for resolution.

What shipments does it impact?

- The allocation order only applies to shipments of the five covered materials described in the box, above. (Please note that FEMA may add additional materials to this order at a future point in time.) Shipments of other materials, including other personal protective equipment, are not covered by this allocation order.
- In order to minimize the disruption of the supply chain and use agency resources efficiently, FEMA and CBP have agreed upon several exemptions to the allocation order. Shipments that fall into one or more of the exemptions (described below) are usually exported automatically and are not subject to detention and FEMA determination.
 - O However, if CBP believes that an exporter is intentionally modifying its shipments to take advantage of one or more exemptions, CBP may detain a shipment and forward information about that shipment (including the basis for CBP's belief of the intentional modification) to FEMA for determination.
 - **o** In addition, CBP may, in its discretion, forward on additional shipments to FEMA for consideration if the agency does not believe a shipment falls clearly into one or more exemptions.
- It is important to note that not every shipment that is detained for FEMA determination will be
 prevented from being exported. FEMA will review every shipment and proceed based on a
 determination of what would be in the national defense interest. As described above, FEMA
 may purchase part or all of the shipment, return part or all of the shipment for domestic
 distribution, or allow part or all of the shipment to be exported.

What exemptions are there to the rule?



- FEMA has decided that the national defense interest dictates that several exemptions should apply. Shipments that are subject to one or more exemption shall not be detained by CBP and will generally be automatically exported.
 - O Please note that CBP may, in its discretion, temporarily detain shipments and forward information about the shipment to FEMA for its review and determination. This will typically happen if CBP believes an exporter is intentionally modifying its shipments to take advantage of one or more exemptions, or if CBP is unable to determine whether a shipment falls into an exemption.
- The initial allocation order provided an exemption for shipments made by or on behalf of U.S.
 manufacturers with continuous export agreements with customers in other countries since at
 least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production
 of covered materials, on a per item basis, was distributed in the United States in the preceding
 12 months.
 - O FEMA and CBP are currently working on procedures for implementing this exemption. Exporters with specific questions about this exemption should reach out to CBP, via the contact information provided at the end of this FAQ.
- The notice published in the Federal Register identifies several additional exemptions:
 - 1. Shipments to U.S. Commonwealths and Territories, Including Guam, American Samoa, Puerto Rico, U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Including Minor Outlying Islands).
 - 2. Exports of Covered Materials by Non-profit or Non-governmental Organizations that are Solely for Donation to Foreign Charities or Governments for Free Distribution (Not Sale) at their Destination(s).
 - 3. Intracompany Transfers of Covered Materials by U.S. Companies from Domestic Facilities to Company-owned or Affiliated Foreign Facilities.
 - 4. Shipments of Covered Materials that are Exported Solely for Assembly in Medical Kits and Diagnostic Testing Kits Destined for U.S. Sale and Delivery.
 - Sealed, Sterile Medical Kits and Diagnostic Testing Kits Where Only a Portion of the Kit is Made Up of One or More Covered Materials That Cannot be Easily Removed Without Damaging the Kits.
 - 6. Declared Diplomatic Shipments from Foreign Embassies and Consulates to their Home Countries. These May be Shipped via Intermediaries (Logistics Providers) but are Shipped from and Consigned to Foreign Governments.
 - 7. Shipments to Overseas U.S. Military Addresses, Foreign Service Posts (e.g., Diplomatic Post Offices), and Embassies.
 - 8. In-Transit Merchandise: Shipments in Transit through the United States with a Foreign Shipper and Consignee, Including Shipments Temporarily Entered into a Warehouse or Temporarily Admitted to a Foreign Trade Zone.
 - 9. Shipments for Which the Final Destination is Canada or Mexico.
 - 10. Shipments by or on behalf of the U.S. Federal Government, including its Military.

How do I know if my shipment falls under one of the exemptions?

• Please review the exemptions described above. Some of the exemptions will be automatically applied by CBP upon receiving information pertaining to the shipment (e.g. if the shipment is being exported to a U.S. territory or commonwealth). Other exemptions require the party



- responsible for the shipment to file a letter of attestation, explaining why one or more exemptions applies.
- If you believe your shipment falls under one of the exemptions that requires a letter of attestation or believe your shipment might be incorrectly detained by CBP, please draft a brief letter of attestation and submit it to CBP with your other export paperwork. FEMA will consider written submissions when determining how to proceed regarding each shipment.

How long will it take for FEMA to make these decisions?

• FEMA and CBP are taking every action possible to minimize the delays caused by this allocation order. FEMA and CBP are targeting a 72 hour timeline from the time a shipment is detained until the time that a response is provided to the owner of the shipment.

What is a "letter of attestation," and how do I submit one?

- A letter of attestation is a letter drafted by a shipment's owner or exporter that provides FEMA
 with key information about the shipment. The letter is used by FEMA to determine whether a
 shipment falls into an exemption and provides critical context about the shipment.
- Letters of attestation are only needed if the shipper plans to export one or more of the covered materials described above.
- Letters should be submitted to CBP through their Automated Export System in conjunction with other export paperwork.

What information should the letter of attestation contain?

- FEMA recommends that you include the following elements in the letter of attestation:
 - 1. Description of the type and quantity of covered materials that are included in the shipment. The materials that are subject to FEMA's allocation order are:
 - N95 Filtering Facepiece Respirators, including devices that are disposable halfface-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;
 - Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181;
 - Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
 - PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
 - PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

If the shipment does not contain any of these covered materials, then there is no need to file the attestation letter, as the shipment falls outside the allocation order.

2. A description of which exemption(s) the owner or exporter believes the shipment falls into. For a full list of the exemptions, please view the <u>allocation order</u> and the



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- subsequent notice (available for public inspection at this link) that FEMA published in the Federal Register.
- 3. A brief statement describing why the claimed exemption applies.
- 4. A brief statement describing the expected end use of the exported materials.
- 5. A statement confirming that the provided information is true and accurate to the best of the exporter's knowledge, and that the exporter is aware that false information is subject to prosecution under the DPA, as described in the allocation order

What do I do if I have additional questions?

- If you have a general question about the allocation order, please contact FEMA's National Business Emergency Operations Center, at NBEOC@max.gov.
- If you have a question about a specific shipment, please contact CBP at covid19exports@cbp.dhs.gov.
- If you have legal questions, please reach out to FEMA at PPE-export@fema.dhs.gov.

